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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/815,242	HASELBECK ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/15/07, 9/17/07, and 2/17/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,31,45-69,77-87,89-96,100,101,103 and 104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12,85,86,89-95, 100* is/are allowed.

6)☒ Claim(s) *31,45-69,77-84,96,101,103 and 104* is/are rejected.

7)☒ Claim(s) *87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed June 15, 2007, Applicant's Amendment filed September 17, 2007 and Applicant's Amendment filed February 17, 2009.

Claims 31, 58-68, 77-84, 87, and 100 have been amended.

Claims 12, 31, 45-69, 77-87, 89-96, 100, 101, 103, and 104 are pending in the instant application.

Response to Amendment

Applicant's Amendments filed September 17, 2007 and February 17, 2009 are acknowledged. It is noted that the instant application complies with the requirements of 37 CFR 1.121(c).

Election/Restrictions

It is noted that in Applicant's election filed March 4, 2003, Applicants elected SEQ ID NO: 1463 as the antisense sequence complementary to the *yphC gene*, SEQ ID NO: 12600 as the *yphC* gene product (polypeptide), and SEQ ID NO: 4228 as the *yphC* nucleic acid encoding the gene product (polypeptide).

In view of this election, SEQ ID NOs. 6154, 6592, 6872, 7273, 7857, 8502, 9420, and 9605 as recited in claim 77; SEQ ID NOs. 1390, 1845, 2782, and 3283 as recited in claim 87; and SEQ ID NOs. 1390, 1845, 2782, and 3283 as recited in claim 104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a

nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on March 4, 2003.

Claims 12, 31, 45-69, 77-87, 89-96, 100, 101, 103, and 104 have been examined on the merits. Additionally, SEQ ID NO:4228 as recited in claim 77, SEQ ID NO:1463 as recited in claim 87, and SEQ ID NO:1463 as recited in claim 104 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

In Applicant's Remarks filed June 15, 2007, Applicants argue that Claim 77 recites the yphC polypeptide from *S. aureus* (i.e. SEQ ID NO:4228) in addition to nucleic acids that encode yphC polypeptides from species other than *S. aureus* (i.e. SEQ ID NOs: 6154, 6592, 6872, 7273, 7857, 8502, 9420, and 9605). Applicants further argue that claims 87 and 104 recite antisense nucleic acid molecules directed against *S. aureus* yphC in addition to SEQ ID NO:1463 (i.e. SEQ ID NOs. 1390, 1845, 2782, and 3283).

Further, regarding claim 77, Applicants argue that they should not be required to cancel the additional SEQ ID NOs: from claim 77 because the nucleic acids of SEQ ID NOs:6154, 6592, 6872, 7273, 7857, 8502, 9420, and 9605 encode yphC polypeptides corresponding to SEQ ID NOs:10251, 10689, 10969, 11370, 11955, 12600, 13518, and 13703, respectively. According to Table VIIA in the instant specification, SEQ ID NOs:

10251, 10689, 10969, 11370, 11955, 13703 have at least 25% amino acid identity to SEQ ID NO:12600. As such, claim 67 encompasses the yphC polypeptides from species other than *S. aureus* that are claimed in claim 77.

In view of these arguments and contentions, Applicants argue that is it improper for the Office to refuse to examine that which Applicants regard as their invention unless the subject matter in a claim lacks unity of invention. Applicants rely on MPEP § 803.02, which states that unity of invention exists where compounds included within a Markush Group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

This argument has been fully considered because the restriction as indicated is proper because regarding claim 77, the claim recites the yphC polypeptide from *S. aureus* in addition to nucleic acids that encode yphC polypeptides from species other than *S. aureus*. The nucleic acids that encode yphC polypeptides from species of *S. aureus* and species other than *S. aureus* have different chemical structures, composed of very different nucleic acid sequences and are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, because the nucleic acids that encode yphC polypeptides from species of *S. aureus* and species other than *S. aureus* have different chemical structures, the prior art applicable to one invention would not likely be applicable to another invention and restriction for examination purposes as indicated is proper.

Therefore, and contrary to Applicant's assertions, the nucleic acids that encode yphC polypeptides from species of *S. aureus* and species other than *S. aureus* as recited in claim 77 lack unity of invention.

With respect to the various antisense nucleic acid recited in claims 87 and 104, Applicants argue that all are complimentary to at least a portion of SEQ ID NO:4228 and serve to decrease the expression of the polypeptide encoded by SEQ ID NO:4228. Thus, Applicants contend that SEQ ID NOs: 1390, 1845, 2872, and 3283 should be examined with the elected invention of SEQ ID NO:1463.

This argument has been fully considered, but is not found persuasive because although the antisense nucleic acids recited in the claims are all complimentary to at least a portion of SEQ ID NO:4228 and serve to decrease the expression of the polypeptide encoded by SEQ ID NO:4228, the antisense nucleic acids recited in the claims have different chemical structures, composed of very different nucleic acid sequences and are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, because the antisense nucleic acids recited in the claims have different chemical structures, the prior art applicable to one invention would not likely be applicable to another invention and restriction for examination purposes as indicated is proper.

Therefore, the antisense nucleic acids recited in the claims have different chemical structures and thus lack unity of invention.

Applicants also argue that assuming that there is no unity of invention, a reasonable number of nucleotide sequences can be claimed in a single application.

Applicants rely on MPEP § 803.04, which states that it has been determined that normally ten sequence constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequence will be examined in a single application without restriction. Applicants contend that in view of this, the antisense nucleic acids recited in the claims should be examined together.

This argument has been fully considered, but is not found persuasive because although the MPEP states that up to 10 sequences are considered reasonable, such guidelines were issued in 1996, and the size of the nucleotide sequence databases has doubled approximately every six months since then. Thus, the number of returned hits for nucleotide sequence searches has expanded dramatically since the time these guidelines were issued. Furthermore, in addition to the voluminous size of such databases, the context in which the sequences appears must also be examined, that is, each potential reference must be read and analyzed to determine if it contains one of the sequences recited in claims 77, 87, or 104. When this is considered in light of the fact that some of the claims read on nucleotide sequences having at least 99%, 95%, 90%, 85%, 80%, 70%, 60%, 50%, 40%, and 25% amino acid identity to SEQ ID NO:12600, such a search may return many thousands of polynucleotide hits. In light of these many variables, this is considered to constitute a serious burden.

Furthermore, the restriction is supported by the Offices' decision to rescind the 1996 waiver (for examining up to 10 dependent and distinct nucleotide sequences). This is based upon the increasing computational, search and examination burden required for the consideration of nucleic acids sequences, and complexity of

claims drawn to such, compared to the time of the 1996 waiver. See the following webstite at: http://www.uspto.gov/web/patents/patog/week13/OG/TOC.htm#ref14.

Accordingly, SEQ ID NOs. 6154, 6592, 6872, 7273, 7857, 8502, 9420, and 9605 as recited in claim 77; SEQ ID NOs. 1390, 1845, 2782, and 3283 as recited in claim 87; and SEQ ID NOs. 1390, 1845, 2782, and 3283 as recited in claim 104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made **FINAL**.

Specification

In the previous Office Action mailed December 14, 2006, the specification was objected to because the specification contained embedded hyperlinks and/or other forms of browser-executable code that are impermissible. **This objection is withdrawn** in view of Applicant's Amendment to the Specification filed June 15, 2007 to remove embedded hyperlinks and/or other forms of browser-executable code from the Specification.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed December 14, 2006, claims 57-69, 78-84, and 87 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicant's

Amendment filed June 15, 2007. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to delete references to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463.

After careful reconsideration of the claims, a new ground(s) of rejection is made of record as detailed below:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 45-69, 77-84, 101, 103, and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 45-69, 77-84, 101, 103, and 104 are indefinite because while the preamble of claim 31 recites, "A method for screening a candidate compound for the ability to reduce cellular proliferation", the method steps conclude with "determining the degree to which said compound inhibits the growth of said sensitized cell relative to a nonsensitized cell". There is not a clear nexus between the purpose of the claim as stated in the preamble and the last method step. Thus, it is unclear how the method steps accomplish the purpose of the claim as stated in the preamble. Claims 45-69, 77-

84, 101, 103, and 104 are included in this rejection because of their dependency therein.

Claims 31, 45-69, 77-84, 101, 103, and 104 are also indefinite because claim 31 recites, "BLASTN version 2.0" and is therefore incomplete because the reference to a computer algorithm is considered to be an improper incorporation by reference to essential subject matter (see MPEP § 608.01(p)). Claims 45-69, 77-84, 101, 103, and 104 are included in this rejection because of their dependency therein.

Claims 31, 45-69, 77-84, 101, 103, and 104 are also indefinite because claims 31, 58-67, and 69 recite, "FASTA version 3.0t78" and is therefore incomplete because the reference to a computer algorithm is considered to be an improper incorporation by reference to essential subject matter (see MPEP § 608.01(p)). Claims 45-57, 68, 77-84, 101, 103, and 104 are included in this rejection because of their dependency therein.

Claims 31, 45-69, 77-84, 101, 103, and 104 are also indefinite because claim 31 recites "under stringent conditions". This recitation is vague and indefinite because the conditions are undefined. Claims 45-69, 77-84, 101, 103, and 104 are included in this rejection because of their dependency therein.

Claims 31, 45-69, 77-84, 101, 103, and 104 are also indefinite because claim 31 recites "under moderate conditions". This recitation is vague and indefinite because the conditions are undefined. Claims 45-69, 77-84, 101, 103, and 104 are included in this rejection because of their dependency therein.

Claim 96 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 96 recites the limitation "wherein growth inhibition" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 12, from which claim 96 depends, never recites the term, "growth inhibition". Appropriate correction is required.

Conclusions

Claims 12, 85, 86, and 89-95 are allowable. Claims 12, 85, 86, and 89-95 are allowable because the prior art does not teach or fairly suggest a method for screening a candidate compound for the ability to reduce cellular proliferation comprising (a) providing a sublethal level of an antisense nucleic acid complementary to a nucleic acid encoding a gene product in a cell to reduce the activity or amount of said gene product, thereby producing a sensitized cell, wherein said gene product's activity or amount is reduced by an antisense comprising SEQ ID NO:1463, provided that the cell is a prokaryotic organism; (b) contacting said sensitized cell with a compound and (c) determining the degree to degree to which said compound inhibits proliferation of said sensitized cell relative to a nonsensitized cell.

Claim 100 is allowable. Claims 100 is allowable because the prior art does not teach or fairly suggest a method for screening a candidate compound for the ability to reduce cellular proliferation comprising (a) providing a sublethal level of an antisense

nucleic acid wherein said antisense nucleic acid reduces the activity or amount of SEQ ID NO:12600, thereby producing a sensitized cell, provided that said sensitized cells is a prokaryotic organism; (b) contacting said sensitized cell with a compound and (c) determining the degree to degree to which said compound inhibits proliferation of said sensitized cell relative to a nonsensitized cell.

Claim 87 is objected to because it contains nonelected subject matter, but would be allowable if rewritten to remove nonelected subject matter. Claim 87 is considered to be free of the prior art since the prior art does not teach or fairly suggest a method for screening a candidate compound for the ability to reduce cellular proliferation comprising (a) providing a sublethal level of an antisense nucleic acid complementary to a nucleic acid encoding a gene product in a cell to reduce the activity or amount of said gene product, thereby producing a sensitized cell, wherein said gene product's activity or amount is reduced by an antisense comprising SEQ ID NO:1463, provided that the cell is a prokaryotic organism; (b) contacting said sensitized cell with a compound and (c) determining the degree to degree to which said compound inhibits proliferation of said sensitized cell relative to a nonsensitized cell, wherein the prokaryotic organism is *Staphylococcus aureus* and wherein the antisense nucleic acid is SEQ ID NO:1463.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, James “Doug” Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

June 19, 2009
/Terra Cotta Gibbs/